UNITED STATES DEPARTMENT OF AGRICULTURE

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NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

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SUBCOMMITTEE 2

PILOT PROJECT TO EXPLORE

MECHANISMS FOR SHARING

INDUSTRY DATA WITH FSIS

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August 8, 2007
3:00 p.m.

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Arlington, Virginia

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I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(3:00 p.m.)

MS. GREEN: I just want to sort of reemphasize, that as we go through your answers to the question, if we could, sort of scope out and walk away with, you get us pointed in the right direction for a pilot project, that would really be where we'd like to go. Like I said, we know we've had a lot of discussions with this group and others about the use of industry data, and we would really like to see if we can move something forward.

Okay. So the first question is, and all of these are in the context of possibly use in allocating inspection resources. So we're talking about for both risk-based inspection for processing facilities and for public health based inspection for poultry facilities, excuse me, slaughter facilities. The first question, what type of industry data would be appropriate for use in a risk-based inspection algorithm for processing establishments? So processing establishments is first. What type of industry data would appropriate for us to receive and

to consider in the context of risk-based inspection?

MR. ELFERING: Does anybody have any questions on those at all?

UNIDENTIFIED SPEAKER: Can I sit at the table?

MR. ELFERING: You certainly can. If you would have been here earlier, I invited everyone up. So if you come late, you're just going to have to move in. Anybody else that would like to join us up here certainly are welcome.

Any questions on that particular issue or question?

DR. CUTTER: This is Cathy Cutter. What kind of data are you looking for specifically that will work with your database system?

MS. GREEN: Well, when we think about risk-based inspection, I know the industry folks can comment, too, volume data plays a very large role in at least the preliminary algorithm as developed and likely in the next version of the algorithm, too. So volume data is of interest to us and pathogen data kind of specifically but if the Subcommittee feels

there might be something else we haven't thought about, we'd entertain that, too.

DR. CUTTER: Okay. Well, I guess the question is from a pathogen standpoint, what -- do you have a system already developed that accepts information or are you working on that?

MS. GREEN: Well, we have our databases that go into a data warehouse and we pull from that to do calculations for risk-based inspection.

DR. CUTTER: So you need something numerical or something --

MS. GREEN: As opposed to qualitative, yes, versus quantitative. Well, on the other hand though, recognizing some of the limitations, I don't know if that's the right word, in some of our discussions with industry, perhaps categories might work. For example, in the first algorithm that came out, I'm trying to think, my mind has drawn a blank, but how many points you might be in the algorithm wasn't necessarily based on a number of positives. It was a range of positives. So in the limitation that maybe industry doesn't want to share with us, actual data,

one of the things that we've been talking to you all about is sharing ranges of data and maybe verifying that. Did that make sense what I just said?

DR. CUTTER: Uh-huh.

MS. GREEN: Okay.

MR. COVINGTON: Can we back up just a second and just give a little brief history of the volume discussions and how FSIS sees volume fitting into this equation as we proceed forward with trying to acquire volume data?

MS. GREEN: In terms of the risk-based -- this is Kim Green. In terms of the risk-based algorithm? Well, it has -- for those of you who have been at our public meetings, it's part of inherent risk and it was a large determining factor, and again there's an inherent risk score and a risk control score. Both of those come together to determine a total score which then as we envisioned it, puts you into a level of inspection, and volume was a large part of the inherent risk. And I'll let Dr. Engeljohn add more.

DR. ENGELJOHN: This is Engeljohn with the

Office of Policy at FSIS. I think looking at volume or generally volume generally is a proxy for us with regards to exposure and in part, it gets to the issue of does the product going into commerce have some likelihood of having a pathogen, a concern on it. So there are other factors that would affect the likelihood of it being present, but volume in and of itself is one of those pieces of information about product that can be fed into a risk assessment in terms of if there's some likely level of contamination and there's a likely amount of it out in the American public, and a certain amount of that is eaten, and the dose response, and all that together, gives some element of risk. So that if there is a higher risk our intention would be to focus more activity where there's higher risk to insure there's greater control.

So the perspective is we see volume as a proxy for exposure.

DR. HARRIS: Let me make a comment. Joe Harris, and obviously we had a lot of discussion at the public meeting on volume regarding this, and

while we did not propose to the Agency the details of how they calculate that in the algorithm, we did make recommendations relative to volume because the original draft algorithm that was put out for comment or put up for discussion, did have volume built into the product inherent risk and one of the challenges with that is the way it was weighted in there is that large plants seem to be somewhat unfairly penalized by volume just from the simple attribute of being large and small plants vice versa, got undue favorability if you will in the algorithm just from their attribute of being small.

And our proposal was to have volume being included in the algorithm more over on the risk control side so that those establishments that were doing an outstanding job of controlling risk would have their volume impact their score at a much lower rate than the one where they were not doing as good a job of controlling risk in which case then volume becomes much more important from the potential exposure of consumers to unsafe or less safe or however you want to phrase that.

So kind of catching you up, I think -- and to date, I don't know that we've seen the Agency's reaction to those comments that came from the public meeting. I've not seen any sort of revisions. So I don't know if we know where we are on that today or not.

DR. ENGELJOHN: Engeljohn again. I would say we haven't given out any new information. I don't think the intention was to do so. The first element as an Agency is how do we actually capture volume, and that is a more complicated issue in the sense that you can capture how much ground beef, product labeled as ground beef goes out the door, how much product that could be used as ground beef goes out the door, and an estimate to that and how you make those estimates. So it really gets down to the issue of what kind of categorization do you need to go with, is included in a category? Are we talking in a day, in a shift, in a week? Those kind of things. So, you know, how it's used is one thing, and our intention is to use it in a risk-based approach in terms of weighting, an where and how that

is a different issue for which we haven't moved further on publicly.

The first issue though is how do we capture data related to that, and as an example for our FSIS inspectors today, when we collect a sample of ground beef, as an example, the inspector checks a box on the form, that says this establishment produced in the range of X amount of pounds, and I think it's in the last 30 days. I can't remember the exact question. Just to give us some perspective about whether or not this establishment produces 1,000 pounds a day versus a million pounds a day, and that's the kind of capture that we have now. The issue becomes one of wanting to get more refinement to that.

The Agency cannot require the establishments to give us that information at this time because it's a paperwork burden that we have to get approval through OMB and because we have an employee in that plant, we can't get that approval. So the issue becomes one, we can make an estimate based on our expert judgment of the inspector in that

plant. If there were some specific records that the plant were to keep that we can make an estimate from or a range from or a very specific number, we would do that but the issue becomes one of how does one go about capturing volume, and then to verify that. So I think that's the first question.

DR. HARRIS: Joe Harris again. As I understand it, for ready-to-eat products, there is a mandatory collection of that data relative to the three alternatives for *Lm*, correct?

DR. ENGELJOHN: For only very specific kind of ready-to-eat products, those that are exposed in the environment after they're made ready-to-eat. And for that, we do have an OMB approval to get that information. We have to seek approval every year from OMB. This last year, it took us a year and a half to get the approval, and in part it's because OMB objects to us forcing industry to give us that information since we have an employee there who could make that estimate.

But right now by regulation, and it's only because we have a regulation, we're able to get that

information. And so for only that category of product do you give us that information on an annual basis, and the parameters of what you give us is whatever you, the establishment, deem to be the appropriate number to put on that sheet.

MR. KOWALCYK: Michael Kowalcyk. When you've mentioned volume, you've talked about ranges. I guess a couple of questions I have up front is, one, what is your anticipated frequency of volume? Is it daily? Is it weekly? Is it yearly? What's the timeframe we're looking at? And is there a specific reason why you would go the route of range rather than the most granular level you can get with the actual volume count? Is it a logistical issue?

MS. GREEN: I think we're looking really and more for this Committee to help us, too, granular is great. We heard from industry there are some concerns there with sharing that, and we heard some of it voiced today. It could be used against them by competitors, that sort of thing. So we only offer up ranges as a potential way again to kind of move this forward, move this off the mark, if you think that is

something that is workable, feasible.

MR. ELFERING: This is Kevin Elfering. And I think that's some of the questions that I'm hearing is that, you know, any of this data again becomes public information and doesn't become something where it's a competitive disadvantage for a particular company. And, you know, unfortunately that's not what it should ever come to, but there are too many times out there that, you know, that's exactly what, you know, all you need is one recall and you've got somebody knocking on your door and who would be very willing to step in place and start selling product and, you know, become very competitive. And is there a way that it can be protected if ever you get it in.

DR. ENGELJOHN: This is Engeljohn, and again it depends on how the information is going to be used. If we were looking at it as an aggregate information, you know, how many pounds of ground beef or how many pounds of sliced luncheon meat, poultry luncheon meat are in the marketplace, that can be an aggregate and that isn't specific. But what the Agency's trying to present here is that if we're

making decisions on an establishment-by-establishment basis, meaning increase the level of inspection or decrease it as a consequence of the level of control that's in that operation, then that in the Agency's view, and I would say from a protection of the data view, that is in essence data that the Government's relying upon for that establishment. We're accepting that data as if it were our own data that we collected. And if we're able or not able to protect that data, then we don't see how we could protect that from industry or from FOIAs. So that's part of the reason why of asking if granularity or ranges can be worked into this, such that we're just trying to segregate, does someone produce again, an extraordinary amount of product in a given day or a given shift or a given week, given a smaller amount so that you can factor whether or not that matters and how much it matters, than the level of detail would be what we would be looking for. And perhaps, if it isn't as specific, then that may not be something that is as of objectionable if it were to be released. But we're looking at it as using that

information for the Government to make a decision about the level of inspection in that establishment.

MS. GREEN: I think one thing to keep in mind, too, is as we move towards risk-based inspection, how this is being done right now, and if we don't have another alternative, would be that the inspectors would be making the estimates that we would use in the algorithm. So I guess one of the questions might be, is there a desire in industry to maybe improve on that.

MR. ELFERING: Another question I have is do you want it on product? Does the volume need to be product specific or just general volume of the entire facility? And, for example, when the Food and Drug Administration conducts an inspection of a facility or a state agency under contract with FDA, they assign establishment size. Like an establishment size 1 is going to be a very small establishment, is probably doing less than $100,000 worth of sales. Would a dollar amount, would that provide you any information that you would need or do you need specific prongs of product? Because these

company, I mean know what their sales volumes are. I mean there's nothing proprietary in any of that, I wouldn't think, you know, and especially if it goes to a range of between 20 million and 25 million and $50 million in sales, is that something that would not be objectionable to the industry but would it still meet your needs?

DR. ENGELJOHN: And I would just say, those are some of the things to consider. I mean we presently have for HACCP size designation, there is a dollar figure there, a very small plant has fewer than 11 employees or no more than $2.5 million in annual sales. So there is that, but that doesn't tell us what they produce and how much they produce.

And as you may recall, part of where the Agency is looking is which products it needs to focus on in an establishment. So an establishment may produce a variety of products. We identified 24 different major categories of types of products when we first started talking about risk-based inspection, meaning whether or not it's a ready-to-eat poultry product versus a ready-to-eat beef product or a raw

beef or raw pork or raw poultry. There are a variety of things there. If we wanted to focus on poultry cuts, as opposed to carcasses, then there's a need for that kind of refinement.

So I think the issue becomes how far down to parse out which products do you need the volume for and some proxy for what that represents. So dollar value may be it, but we're still looking to try to get at what type of products are produced and how much so that we can use that in a form of being able to figure some proxy for exposure.

MR. ELFERING: This is Kevin Elfering again. Don't you already have all of that on your establishment profile though. And is that something that you can just add to an establishment profile and send it into the PBIS system that that profile is updated?

DR. ENGELJOHN: We'd like to do that but who do we get that number from? I want that number. So I can easily put that in the profile, which is part of what we would like to be able to do, and it just comes up once a week or once a day. Is this

number changed by, you know, more than 10 percent or less, and come up with something, just say has this changed or, you know, in order capture that kind of change. We can easily do that but the issue becomes where does the number come from?

MR. ELFERING: Yes, sir.

DR. YANCY: Al Yancy, U.S. Poultry and Egg Association. I remember that there were two issues during the volume conversation and, Joe, you hit very well on the first and I wouldn't say the most critical, but certainly the primary one because it was the first one brought out.

But to Dr. Engeljohn's point, I think the second one is certainly critical for the Subcommittee to consider, and that is volume of what? Volume of pounds produced or volume of pounds shipped? And to my recollection, there was a great debate on that issue, and where U.S. Poultry and Egg came down on it was that it should be based on pounds of product shipped, not produced.

I remember there was some in the Agency that said, well, you don't produce product not to

ship it. I agree. But there are opportunities for plants to find and arrest product before it gets out the door, and address those problems, and if a plant is forced to count the pounds that are produced, versus the pounds that are actually shipped, plants that have hold, test and release for *Lm* for example, when they unfortunately get a positive for *Lm*, that's going to be deleterious to them if it's counted as pounds produced. If it's pounds shipped, that product never left the plant. It'll either get condemned or re-cooked, and it won't get released until it's got a negative *Lm* result. That's just one example of how pounds shipped is more relevant in the opinion of several in the industry, U.S. Poultry and Egg being one, versus pounds produced.

DR. ENGELJOHN: And if I could just on that point, this is Engeljohn again, but technically for the Agency, if it's produced, it's what's available for commerce, it's what's shipped. So we could quibble about the language, but I would say we would agree. What's going out the door for an intended use or likely use would be what we're talking about here,

and again, if it was for further processing in another plant, that, that we would hope to be able to capture in some way so that our inspection activity in that first plant would be different than what we would do in the ultimate plant where it would be made up. To use the corndog example, where the hotdog is being made in one plant. By reg, it has to be a ready to eat product, it can't have detectable *Listeria* but it's going into a corndog, which is a not ready-to-eat product. And so would the Agency want to invest the same amount of resources inspecting that hotdog and the sanitation and so forth in the same manner as it would as if that hotdog was going out the door to the consumer as a hotdog? And so we've set up the process such that as long as it's identified as being produced for further processing, that we handle and treat it differently. We don't test it for *Listeria* at that operation because it's going for a not ready.

So it would be those kinds of things that could be built into a system, but I think you get at the point of what is its intended use or what is its

likely use as it goes out the door and how much of that, and to be able to categorize that I think is really getting down to the point of what it is we mean.

MR. ELFERING: Any other questions or comments?

MS. GREEN: Maybe one question to sort of stimulate some discussion here. As industry knows or as most folks probably know, we're doing a volume extension. Our inspectors are doing it now. So they are making these estimates on your behalf of what your production volume is that we have used in our preliminary algorithm and probably would use as we go forward.

What is the level of confidence -- well, what would I say? Let me get your perspective on the level of confidence of that and are you comfortable with that being how we go forward? I guess the question would be would you like it to be -- we'd like it, you know, a number that we feel very confident about.

MR. ELFERING: Yes, Joe, go ahead.

DR. HARRIS: Well, I'll at least give you one reaction to that. Obviously they are making certain estimates now. As to my understanding, those are sort of on their own in being used. I would suggest that if the Agency is going to rely on those estimates and if that winds up being a recommendation, that we continue to use those estimates, that might be something that could be reviewed with plant management at the weekly meetings. I know we're already under a scenario where the IIC has a weekly meeting with plant management. At the very least, I would think that we should have the inspector review his estimates with plant management and at least get plant management some opportunity to say, oh, no, no, no, you're way off base or not. Relative to how close they are, I have no earthly idea other than unless they're sharing those with plant management, to get some sort of blessing on are they in the ballpark or not.

MR. ELFERING: So in other words, the recommendation then would be that the Agency continue to gather this information by the IIC and verified

with having some type of verification with plant management? Does that -- yes, go right ahead.

MR. WINTHROP: This is Jay Winthrop with the American Association of Meat Processors. Expanding on what Joe's saying, I would find it very difficult. I mean the first thing, the meetings, the weekly meetings that occur, have got to be up front and completely transparent that the plant management knows that this is what it's being used for and whatnot.

But furthermore, on top of that, to look at it from the fact of we have a lot of plants under a patrol system where an inspector may be only physically at the plant for 2 hours out of an 8 hour shift. How then can he draw an estimate out of such a short period of time, other than to ask directly to plant management how much pounds have you produced?

MR. ELFERING: Yes, go ahead.

MS. NESTOR: Felicia Nestor, Food and Water Watch. From a consumer standpoint, I think one thing that we're worried about is that if you use some method which can then be challenged in Court, sort of

like the *Salmonella* testing system was. I mean it doesn't do us any good if we use some system for three or four years and you take some action at a plant based on an estimate, and then the industry takes you to Court, and it's determined that it's invalid.

Building on the idea of coming to some sort of agreement between the inspector and the plant for instance, through a work unit meeting, from a legal standpoint, I think the Agency would be better off if the inspector proposes to the plant, this is what I think your volume is, and the plant then signs off on it or doesn't sign off on it. So the plant would ratify the inspector's estimate. So then the plant could be held accountable to the inspector's estimate. So I'm just saying this from the point of view of having it be a legally enforceable estimate.

MR. FINNEGAN: Mike Finnegan. Do I understand this right, that if we do get this information that it is kept confidential or not per plant, not per aggregate area? Is it -- this information we get, is it going to be confidential?

DR. ENGELJOHN: And it's not an easy answer to the question from the perspective that again it's how it's used in part that determines whether or not it's proprietary. I mean what we would go through in any FOIA request that we would get, is our attorneys would make some decision about whether or not it fits into any of the exclusions that could be there. The point being, that if a number which today the Agency uses to make inspection decisions, and as a consequence, today it would be releasable. I mean it would be one of those records that a determination would be made on a case-by-case basis, but we make Government related inspection decisions about it. And so from that perspective, it is a critical piece of information that has to meet a -- the level of scrutiny that it goes through is whether or not it can be prevented from being released, is rather law because again it is something for which we use for decision making in the first place.

MR. FINNEGAN: Okay. So if an inspector goes and addresses a plant, the plant has to know up front that it's possible that this information -- I

don't know why they want to keep it for volume, but it could be public. It could be on the USDA website or --

DR. ENGELJOHN: I would just opine that the Agency would not have the intention to make it freely available.

MR. FINNEGAN: Right.

DR. ENGELJOHN: It would be something for which a request would have to be there, but it would be a piece of information, just like anything else we put in the plant profile, on the PBIS right now, information that's used to make decisions about, and a determination would be made on a case-by-case basis.

MR. FINNEGAN: It would just seem to me that if we could insure some confidentiality, they'd be a lot more willing to divulge the information.

MR. ELFERING: Michael.

MR. KOWALCYK: Thank you. Michael Kowalcyk. Yeah, I think if the Agency was going to rely on estimates that are made at the plant, we certainly need to develop a way to validate those

estimates, especially if you were going to use something that would go into an algorithm that would then drive inspection practices because Felicia brought up the possibility that it would not hold up to the standards legally to be defendable.

And also a simple misunderstanding. The gentleman across the table, mentioned product shipped, product produced. Well, the inspector could be estimating product produced and the plant manager's saying, no, this is the product shipped. In the sense, they're both right but which one do you use? So I think some way to validate that would need to be addressed.

DR. ENGELJOHN: I think that that raises some really good points in terms of, regardless of what is used, I do think there should be some principles identified. At least there needs to be a full description of what it is you're asking for with some examples so that there can be perhaps a dialogue so that the person who's recording it or collecting it, would know exactly what the intention is, so that that's much, much better defined than we have today

which there is no clarify as to what really is it that's encompassed here. So I think that would be very helpful to insure that that gets done.

MR. ELFERING: Brian and then Mike.

MR. COVINGTON: Okay. I just want to follow up on Mike's question and answer. And this expounds a little bit -- well, it does expound outside of the volume arena which we'll get to but currently, according to 5000.2, the Agency has the ability to review any plant information that's collected that's used to make a food safety decision, i.e. any support, justification documentation, fire hazard analysis. So with that, that would be confidential information for the plant in which volume could be in some products, would be included in the hazard analysis because it could affect the potential for a food safety hazard.

Now having said that, there's some language in the Poultry Inspection Act that basically leads to the fact that the Agency has the right to view this information, confidential information, but they can't share it outside of the Government. And then there's

some language in the HACCP Final Rule that talks about some exceptions to FOIA requests when it comes to HACCP records and confidential information. So I guess maybe some clarification on how this information would flow into that, with the establishment's right to keep that protected as proprietary or confidential versus having it available to a FOIA request because, you know, that's when you start getting into the statutes and the legality of this whole discussion.

DR. ENGELJOHN: To answer the question, this is Engeljohn, presently the information that the judgments the inspector makes about the HACCP system and that food safety system, is something that's kept at the plant. The Agency doesn't pull those records and put it into its record system. And so that's the reason why that information is that we don't release that through an FOIA because we don't actually have possession of it.

But once we take possession of it and use it, then it does get into the scenario that it is under the Government's possession, and then a

decision gets made on a case-by-case basis as to whether or not it's confidential and proprietary and all those decisions. So that gets made on a case-by-case basis.

So our issue though is, we're taking the information on a plant-by-plant basis to make decisions about how inspection activity is conducted in that plant. It is our view at this time that that information likely would not be protected on a FOIA case-by-case basis. Just like any other information the Agency collects on that establishment. Every single inspection finding that we have is releasable. Every micro result is releasable, and it would be the same here. That's our opinion today, and that may be challenged and we may come up with further refinement to it, but I think we should work under the principles that that's what it is we're working under right now.

MR. ELFERING: Michael, you had a question?

DR. RYBOLT: This is Michael Rybolt. Brian actually asked the question I was going to ask, but I guess that's where I'm still confused because the

data that you collect, the *Salmonella* data that you collect, is FOIA-able because it's information that you collect, but if it's information that the plant is collecting as part of its HACCP plan, I guess that's where we're trying to figure out how it's not protected under that.

DR. ENGELJOHN: Our intention is to take that information about volume, in this case volume just being one of the factors that we would like to rely upon, and use that to make a decision about scheduling, about activity, and so it's much like the information on the 10240 form now, that information influences what we do in that plant with regards to inspection activity. It is not protected.

MR. ELFERING: Ms. Nestor, and then we are going to need to come to some kind of a conclusion here and we're going to keep talking about volume. I thought these were supposed to be easy. Ms. Nestor.

MS. NESTOR: Felicia Nestor, Food and Water Watch. I had an idea and now I think I've poked holes in my own idea, but I'm going to offer it

anyway just to see if it pushes any. What about, you know, the inspectors get an instruction to sample at a plant. What about if the plant declared their volume and then either on a random basis FSIS instructed the inspector to verify it or the inspector at his or her own discretion could say, today I'm going to ask you to show me all of your sales records for today's production. Now I don't know how people keep records, but aren't plants required to keep records for trace back purposes?

DR. ENGELJOHN: This is Engeljohn. Yes, that's correct. Every single amount of product produced, there's a bill of lading for by regulation and by statute. All that's there. There isn't a regulation that says you have to accumulate it throughout the day and end up with a tally at the end of the day. If there was, that would be the perfect piece of information we could go to and just verify against. And if the industry were to voluntarily decide we're just going to do it that way, and identify, we're going to keep this record and it's going to be titled such and such, then we could

direct the inspectors to go and find out from the plant if they have that, and if so, verify that, take that number and just, you know, because that's the number that you're going to be using, and it's verifiable if we needed to verify it.

For those establishments that chose not to do that, then we need another mechanism to be able to get at it, but it sort of gets at your issue. Yes, they're required to have this information by regulation and by statute, but not in a form for which it's tallied and readily accessible.

MS. NESTOR: But if you did it on such an intermittent level, would you still have the problem with OMB? I mean could you declare that the inspectors could come two or three times a year and require them to give you the bills of lading for that day?

DR. ENGELJOHN: Well, actually we can do that today. The issue is do I want the inspector spending 8 hours adding tally sheets, you know? And, no, I particularly want to although we think volume is a critical issue that could have an influence on

public health protection. The issue would be how could it be done in a manner that's most efficient and effective, that is of a means for which it can be verifiable in some fashion? It's no problem for the inspector to make that estimate and ask the establishment if they agree or not or would have records to verify that in some way. They could do that. It's just asking the industry to give us the information is one for which I have to seek approval for, and one for which I already know wouldn't be able to get easily. And so the issue is then what's the alternative? The alternative is to find voluntarily maintaining some form in some consistent manner or the inspector making that judgment, and getting it verified or ratified or accepted or cleared off on by the plant. That's not an issue.

MR. ELFERING: Well, we need to move on but Kim just gave me what the Agency currently collects as kind of a range, where the inspector would mark off the typically produced amount of product in a day, and that's across all shifts. The first one would be none. The next range was 1 to 50 pounds.

The next range is 51 to 250. The next one is 251 to 500, 500 to 2,000, 2,000 to 10,000, 10,000 to 50,000. And these ranges, would that be something that the industry would be willing to provide FSIS? In those ranges.

MR. COVINGTON: I can speak for my company and within those ranges, it's a pretty easy answer for us, and with a lot of other companies because they are so small from the top to the bottom, you know, that we could very easily say, yeah, we produced over the 50,000 pound limit, but I still think it gets back to you do not have a good estimation even at that level as to how much we produce because a very large grinding establishment may produce 600, 700,000 pounds a day. To say over 50,000, it's still not fair to put somebody produces 75,000 in with somebody producing 600,000 pounds.

MS. GREEN: And, Brian, I guess one of the things, if you were willing to do, I think we would definitely want to revisit those ranges and certainly get industry input on something that might be more appropriate, but I guess floating the idea by you

all, if --

MR. COVINGTON: Yeah, and I think we would probably be open to that, but I think getting back to Joe's comment earlier, I think we would have to define product category, process category, because you take a beef slaughter operation, how do you determine that volume? Is it carcass weight or is it cutout weight? Because you've got a lot of product that's a lot of weight that's not being inspected because it's inedible product. So that would be, you know, the next discussion.

DR. YANCY: Al Yancy, U.S. Poultry and Egg, and I think that was one more of the multitude of reasons why I was focusing on pounds shipped because that gets to the heart of what you're talking about. It gets to the *Lm* example that I've spoke about which Dr. Engeljohn has spoken to, but it gets right to the heart of what you've just said. You've got your product categories because you know exactly how many pounds of product code 1, 2, 3 you produced, how many you produced of 4, 5, 6, and that tells you whether it's ready-to-eat, ready-to-cook, and all the other

information that you would want to know.

So pounds shipped to me again to that very issue gets what you want more so than pounds produced, and it takes that whole issue of what you've just covered which is a valid question and takes that off the table.

MR. ELFERING: Okay. Let's go back to the original question. We've been discussing volume. We really never even touched on some of the other issues. So we need to get some kind of a recommendation. So shall we go over -- the question is what type of industry data would be appropriate for use in a risk-based inspection algorithm for processing establishments, in its presence or absence, enumeration, serotype, subtype data, for pathogens in product? We also have plant environmental monitoring data. Maybe we should take these. We talked about volume a lot. What about the very first bullet, presence or absence, enumeration, serotype, subtype data, for pathogens in product? Dr. Engeljohn.

DR. ENGELJOHN: This is Engeljohn. If I

could just give some perspective here, maybe to get the thought process going.

The industry does a substantial amount of testing overall in some establishments, an exceptional amount of testing, and the issue becomes one of they have that program in place, it presents some obviously risk control in the sense that product is diverted from the raw product marketplace, if it's raw beef trimmings as an example. And there is no means by which we capture that now to say that a program designed such to have high level of competence of finding a low level of pathogen, to give credit to that, so that, in fact, that's recognized. That's one thing.

Defining the sampling procedures is another, and within the beef industry, that's fairly well defined now. There's some standardized methods that the industry is doing, and so that it's probably a little easier to proceed with that.

But also, if we knew how much product, the industry itself, what its percent positive rate was, as FSIS tracks its percent positive rate of product

produced, but if industry itself was sharing or providing the information on how much was tested, what the percent positive rate was, it would help give some perspective about the national trends or what's out there, what's being diverted, what's not going into the marketplace, so that if, in fact, there's evidence of increased numbers of positives, that you're diverting out of the market, capturing that information would in some fashion as well perhaps help us predict that there's a high prevalence season starting, or it's occurring in a particular region. And we would never know that through our own limited amount of testing that occurs in a plant where we may be there in some cases no more than four times a year or in other cases, maybe once a month. So it's a way to capture that information and try to find a way to use it to make predictions about how public health protection was put in place, what the exposure was likely and to use the vast amount of industry data to supplement the limited amount that the Agency has. So that's part of the reasoning behind why that could be very

helpful to the Agency.

MR. ELFERING: This is Kevin Elfering. I've got one question. This is a voluntary program. Do you think you would ever get anybody to volunteer?

DR. ENGELJOHN: From my perspective, the issue is why not? If the issue is -- and again I would just say within the federal program, there has always been concern about how inspectors would react to positive tests that the plant finds. And our goal has been to insure that our employees are trained sufficient such that they react appropriately, the goal being to find the pathogen and to remove it and to get credit for that as opposed to getting dinged for looking for it and finding it. And so this would be a means to help better insure that we're taking the appropriate actions. I don't know why there would be objections to that.

MR. ELFERING: But I think one of the things to consider, and I think one of the representatives of the -- probably was even the Veterinarians Association, they're already looking at this data, either the IIC or from some type of a

supervisory standpoint. Isn't that system in place that if there is a significant issue with positive results that controls are taken at the plant level and if it needs to be, can be escalated to the district level and from there, if need be? So is there really a true need? Do you already have the system in place to deal with this or do you feel like this information needs to come into Headquarters?

DR. ENGELJOHN: And if I could respond. The reason why we're looking at a way to enhance that is that we don't collect or document or tally that information now in any records. So there's observations made but there is no collection of that and used in any way in terms of Agency decision making other than on a case-by-case basis by the inspector in that plant. The issue here being that if the percent positive rate or if the -- as the Agency's doing now is taking its positive isolates for *Salmonella* in the raw product program and putting that into PulseNet, so that we can better get some perspective as to what is the type of exposure of pathogens to humans in the products we regulate and

then what are they getting sick from. If the industry is testing every day, multiple times a day and they're finding positives, and they know what types of *Salmonella,* as an example, are prevalent in their operation, that information into a system to look at what's available to the consumer, helps get at the issue of attribution. It helps give a better perspective of what's going into the marketplace and is a likely exposure to the public. And that's what we're trying to get at.

MR. ELFERING: Yes. Isabel.

DR. WALLS: Hi, Isabel Walls. Coupled with that, what would be really useful for us is what interventions industry is using to eliminate the pathogens so that we can look at these from the perspective of, you know, what's effective. And as we consider, you know, inspection, if we see such intervention as being particularly effective, we could look at that like with *Listeria*, you know, looking at risk-based testing let's say. If we know certain interventions are effective, that would be very helpful. Right now we do not know which

companies are using which interventions, and again, it's not something I think we're allowed to ask. So it's a data gap, and I think if we're thinking of doing a pilot that would include either volume or pathogen, I think intervention would be really, really helpful to us and globally to everybody.

DR. RYBOLT: This is Michael with the Turkey Federation. The problem with knowing what interventions work is that, you know, during the meetings that we've had discussions with our tech and reg members and -- the different technologies symposiums we've had, is you can take that information from one plant, and it may work in that one plant, but it's not going to work over here in this other plant. So I don't know. Maybe you would get enough information to be able to make a determination about what works, but from our discussions, so far, as we've had the same people doing the same thing, it didn't work, and they were essentially the same operation except they were different companies.

DR. WALLS: I still think that, you know,

the *Listeria* regulation is a good model, where we have specific interventions like, you know, if it's no post-packaging exposure, let's say or if it relied on sanitation alone, and if we could come up with something similar let's say for *E. coli* O157:H7 or *Salmonella* in chicken, you know, the bigger picture down the road, that's going to be very helpful to us.

DR. RYBOLT: But you're talking a RTE product versus raw product, too. There's a difference.

DR. WALLS: True. But, you know, steam pasteurization has been very effective on raw product on the whole or water rinses. There are interventions that work on raw product.

MR. COVINGTON: A question for Dr. Cutter, being a microbiologist. Do we have enough or for the Agency, do we have enough information on the different *Salmonella* serotypes as far as their ability to survive in different climates and how we get kill on some of these different types of organisms? Because I mean *Lm* is one organism. O157 is one organism, and then we've got *Salmonella*

enteritidis Kentucky. You've got all these different ones. I mean do they react differently?

DR. CUTTER: My data is somewhat limited. We do know that whatever interventions we're doing for *Salmonella* will control DT104. We know that there are other interventions that can control, you know, similar organisms, but I don't think there's enough information out there to truly determine whether one intervention fits all. Would you agree, Dan?

DR. ENGELJOHN: Yes, we absolutely do agree with that but I'll just use the example of online reprocessing which is an area where we have some knowledge as to which types of interventions are in place within those operations because they seek prior approval from us, and just knowing what they have in place through their no objection letter, and then looking at their *Salmonella* data or looking at their NR data, not that you can make definitive cause and effect determinations, but you can see that those operations that use this type of intervention perhaps have this general type of percent positive rate in

terms of our testing versus another such study could lead us to at least provide guidance to say for operations using certain types of interventions, we would want them to focus on sanitation, or we would want the industry to know that. Or it would be something for which we could raise with our industry or research partners to say, some things don't seem to be as effective. Could you study this? So capturing what's being done is one thing. How effective it is, is another. That's sort of what we've done with the *Listeria* program where we ask what's being done, how much do you produce, what's your testing frequency, things like that, to capture this general information that can be used in a general way to see if there are associations. But I would agree right now for the raw products, they all have some degree of effectiveness, and in combination, they may or may not have more but knowing who has what, is an issue for which we do think has some relevance.

MR. ELFERING: You had a question?

DR. YANCY: Al Yancy, U.S. Poultry and Egg.

I've spoken to several of our constituents in the broiler industry, none in the turkey industry, about the *Salmonella* issue, the *Salmonella* initiative, and the general consensus is that serotyping is a good thing. Subtyping, it's not been part of my conversation but serotyping is a good thing, enumeration is a good thing, and I think that the broiler industry, a majority of them, if not probably all of them, on some level support that. I don't see but one problem potentially with tracking the intervention OLR or any other for that matter that a company uses. And that one problem is a significant one, and that would be drawing inferences that are broad, such as this intervention seems to be the best one or ranking them in some way, shape or form.

I think it might be very constructive because I think what it will prove is just what Michael has said, which is empirical but no one has significant amounts of data that they're willing to share that says what he said. But we all know that it's true. We've seen those examples, and I think collecting this information will show that, and I

think there is a misconception that we all have the answer. We're just not willing to implement it or we don't want to spend the money to implement it. True, when we get in trouble, we find whatever we need to, to get to the problem, but what works today doesn't necessarily always work.

So I think tracking that information would be good. It may teach a lot of us, including myself, something but I think what it will show is exactly what Michael said, that some things work better in some cases than others, and there is no one specific system that is the best one.

DR. RYBOLT: Kevin, this is Michael again.

MR. ELFERING: Michael.

DR. RYBOLT: This is Michael Rybolt again. Al actually articulated better what I was saying. I'm not saying that we shouldn't look at the information. It's just the inference that may be drawn from it. There have been instances before where somebody says, oh, it worked over here. You better use it. And it does not need to be dictated because the plants, their food safety people working

with their inspectors, need to decide what works best for them, and it can't be one particular, and I think you understand that, but I just want to make sure it was articulated. And, of course, Al did it better, but also on a serotype issue in the subtyping, we've talked within our constituency about, too, as well, and the problem is collecting that information is good, tracking that information is good. But when you start getting into serotype with *Salmonella* because there is so many of them, you have to be extremely careful not to say that, well, all the hazards come from turkeys. All the hazards that are in humans come from turkeys, because you don't know how many *Salmonella* hazards are coming from the tomato outbreaks.

I can't remember what serotype it was in the peanut butter but, you know, some of those other places where we're not getting the serotype information from and some of the lack of reporting *Salmonella* outbreaks. And again, we get into PFGEs. It's exactly the same thing. Just because you're seeing a lot of it from turkey, well, maybe that's

because that happens to be the one that is the most common among all the different possible vehicles out there. So we've got to be careful, having that information is good information and information that industry should take a look at, and that the Agency should take a look at, but I don't necessarily say that that is the direct causal relationship. So we just need to be careful there.

MR. ELFERING: Yes, Jay.

MR. WINTHROP: Jay Winthrop with AAMP. As I look at the list that's up there, and you consider the fact that anywhere from 90 to 95 percent of the USDA plants are small and very small plants, are you worried about a consistency issue basically because a lot of the small guys probably aren't carrying out near the testing, nor going near the extreme some of the large companies are. And the data's just not going to be there, whereas volume, it's a pretty easy quantifiable number that everybody can measure.

MS. GREEN: I think we still some utility again, as we said before, when we sort of view this. We do see it as voluntary but as Dr. Engeljohn has

made reference to, too, when you sort of look about, you know, where we're trying to go with risk-based inspection, it is the larger volume plants that we're interested in, and they are going to be the ones that have some of this data.

DR. YANCY: Al Yancy. Just one quick point. I want to make sure that that at this point is clear as well, is that there is a vast amount of *Salmonella* data, but that percentage of it that is serotyped, that percentage of it, which is enumerated in that order, is markedly decreased. Most of what the industry has is plus, minus, plus, minus, plus, minus. Very little and very little serotype and almost no, not no, but approaching no comparatively speaking enumeration. It's done in cases where the plant is really in trouble, they're trying to get to the bottom of the situation, or they're testing some new processes to try to make sure that those processes are going to do for them what they want, whether they're in trouble or not. It's not a consistent thing in any company of which I'm aware.

So the vast majority of the data,

historical and even present, that exists is plus, minus only.

MR. ELFERING: Okay. We need -- Michael, you have a question. We need to formulate a response here.

MR. KOWALCYK: I'll try to be brief. With respect to the enumeration issue, is that because -- it is more cost prohibitive to do that and collect that data. Is that why industry tends to just look at the plus or minus movement of it?

DR. YANCY: Two reasons, not specifically the only two but these are the two big ones. Cost prohibitive and a side bar on that is availability in that who can do it and how much time it takes and how much it costs. All those things are wrapped into one, and the other is why? And that's what I've been harping on. That's what the industry on now is what's the point of knowing exactly how many cells when we're dealing with a plus, minus issue?

So that's why I say that the broiler industry is getting more and more invigorated about doing exactly what the Agency is talking about doing

which is looking at enumeration. We're saying we need to go farther in that direction, and I think the capacity and the costing will be driven by the business. When more people want to do it because there's a reason to do it, i.e. it's science driven instead of the other, I think that capacity will come along and the availability and the costing will come down.

MR. KOWALCYK: And one other comment about the data either being voluntarily collected or even requiring that it's collected. My concern is, I mean it was brought up with respect to the small producers, and there was a comment made about you're interested really in the larger facilities. Now does that mean that -- I mean they're all regulated under the same regulations, and if the Agency is going to roll out RBI across the entire industry, does that mean that there's going to be basically a different strata of plants based on their production volume and will they have different algorithms? Because I mean the volume range is a big issue, where you're in the top range, half a million pounds per day, versus a

quarter of a million pounds per day, this is a substantial difference when you look at the actual data, but they would both be in that same large bucket. And I'm just trying to wrap my head around if that data is going to be voluntarily submitted to the Agency, could there be some self-selection bias in that information in applying that to the entire industry could become problematic.

MS. GREEN: I think bias is something we would definitely have to look at, but on the other hand, if we don't get the accurate estimates from industry, for whatever we might be looking at, be it pathogen data or volume data, don't get accurate data, we will be relying on what data we have. So we see some benefits in making it as accurate as you can.

On the other note, you just gave me something. You know, we're really trying to work on and look at what the next algorithm should be. You just gave me another idea.

MR. ELFERING: You can't add anything on here.

MR. KOWALCYK: I apologize to the Chairman.

MR. ELFERING: Okay. If we were to formulate a response, to this question, the Committee makes the following recommendations for question 1. A, how would you answer that? Any suggestions from the Committee?

If enumeration and serotyping information is not being captured right now by plants, it's pretty meaningless to ask for it. So if there would be a voluntary program and a plant that would volunteer for this, would it be just the presence and absence.

UNIDENTIFIED SPEAKER: That's what they're doing now. That's all we can ask for.

MR. ELFERING: Okay. And how about plant environmental monitoring data including presence and absence, enumeration, serotype, subtype, data for pathogens? I would -- the question first of all, how many plants are doing any type of environmental testing other than for *Lm*? Is any plants doing any other type of environmental? So really that probably would not be readily available at all.

DR. ENGELJOHN: Just as a suggestion to be thinking about in the *Salmonella* initiative meeting we had in February 2006, we had some research present information that the equipment, the scalding equipment, the pickers, are known to be, unless they're appropriately sanitized, can, in fact, be the cause for recontamination or a source of *Salmonella* or *Campylobacter* that isn't removed from the prior flock or the prior day. And so I would contend that there are individuals out there who are looking, not just with *Listeria* but looking to make sure that equipment and other sources are not part of the contamination problem.

MR. ELFERING: But that again would be presence and absence very likely. If there is environmental testing being done in those plants, it would be just for presence and absence.

DR. YANCY: Al Yancy, U.S. Poultry and Egg. I know the Committee's making this recommendation, so I don't want to misspeak, but just very briefly. I would venture a guess that the data that exists for any environmental which would probably be much

smaller than anything else I've spoken about to this point, most environmental testing, if not -- well, the vast majority of it is *Lm,* and you've covered that.

Any other environmental or equipment testing would have been part of, in most all cases, an operational sanitation issue, not a pre-operational, because the thought process is in these cases, even if it's clean when you start, the minute you start running, you've already contaminated those surfaces with *Salmonella* and it's what you do during the process, not necessarily before the process. So any other data that was gathered would be almost entirely operational rather than pre-operational and I would be willing to bet that it's plus, minus, like everything else.

DR. ENGELJOHN: One other example then, just so we're aware of all the issues, but in terms of *Salmonella* control in poultry in particular, swabbing the houses, doing drags there, and bringing data along with the birds to the slaughter facility, is one way that an operation would know whether their

system is designed to address the pathogens coming in and perhaps the load of pathogens if they're looking to see what's coming to the slaughter facility. So that's another form of environmental testing that industry does do that could, in fact, be something that could feed into a mechanism to be protective of public health.

DR. YANCY: For that information, you may very well have some serotyping. In those cases that Dr. Engeljohn has brought up, I was thinking environmental as in the plant that -- he's thinking much more open and broader and that's a good thing. I agree with him. That data is probably -- there is drag swabs. There are litter samples, and in those cases, a lot of it is plus, minus but you probably have the best chance in some of those cases of actually getting some serotyping.

DR. NEGRON-BRAVO: Edna Negron. I just want to raise a question. Is that too difficult to get information from the industry on what they are doing? You know, just like a tally with the inspectors. We're assuming, and I assume it's right,

most of them will be plus and minus. I agree with that but we could ask and get for future information, ask them, what kind of information are you getting in your analysis, just plus or minus or enumeration, and get a feeling for next time, like doing a survey kind of information, because that could be easy to get it.

DR. ELFERING: So in other words, really we could formulate this that whatever the plant does, if they do presence, absence, that's what's going to be available to you. I would think serotyping would be real difficult with drag swabs.

MR. FINNEGAN: Mike Finnegan. Inspectors in ready-to-eat plants, part of their risk or part of their tasks is to go look at the ready-to-eat. Is that right? I mean do they have to do so much sampling? Don't we have to look at the environmental sampling? I mean so we would have that through the inspector, would we not, you know, the results because it's plant environmental monitoring data? Would that not be available to each inspector in the ready-to-eat?

DR. ENGELJOHN: Well, if the plant has it,

the inspector could view it and verify it but the inspector doesn't collect that today. The issue here is finding information industry may have to supplement that which the Agency has to better inform what is the control and what is the level of control in a particular operation?

MR. FINNEGAN: I was thinking more of looking at the plant's records for environmental sampling and if it be a plus or minus, if you've got *Lm* or not. It has to be available. You know, couldn't we gather some of that information from the inspectors is what I'm asking here?

MR. ELFERING: As I'm trying to formulate a response here to, it's getting more difficult. If you were to have 10 plants that would volunteer for this, and three of them did enumeration and serotyping, and the rest of them didn't, would that skew your data? So would you want -- I mean the most you're going to get in some plants is presence and absence. Would you not want that all from all the plants and nothing more?

DR. ENGELJOHN: Well, if we're talking

poultry here in terms and this was an initiative related -- the issue would be for consistency, but the point is trying to use the data to be better predictive of what is, in fact, the impact on public health. And the Agency has a very limited amount of data that we collect, the Agency does. The industry has a substantial amount that they're likely collecting, and together could give a bigger, better picture of what is, in fact, happening with product going out the door. That's the purpose of getting the information. Plus or minus gives us one thing. More descriptive information that's characterized gives a far more specific picture and can be better used in terms of getting at an attribution issue. So it's just degrees, how much is available can be used one way. If there's more information, you can use it in another.

MR. ELFERING: So if there would be more information available, you would want it even if it was just from a small portion of the plants?

MS. GREEN: Yes, but I think also to go back to Mike's question a little bit, I think the

model you gave is something that we might be able to work with, too. Obviously there would be issues that we would have to work out. And that goes to when I was talking about a pilot project sort of having two models. Give us data or we verify data. So that might be something we could work with, too.

And while they're not specific questions, Kevin, I am kind of hoping we, you know, to the extent that we could wrap these around a pilot project, we'd be very grateful.

MR. FINNEGAN: What I'm referring to is the plant environmental monitoring data, just that. I know that's available to the inspectors. The inspectors could write it down, keep track of it. I don't see why not.

MR. ELFERING: Yes, Michael.

MR. KOWALCYK: Michael Kowalcyk. We're talking about, you know, it seems to be going in the way of, you know, presence or absence of pathogens, environmental testing. Are you at a point where you can share with us a little bit about if you had that, I'm thinking of, you know, just how the data would

look for that, and does that meet your expectations for whatever this algorithm is going to be, and basically I'm trying to get a sense for what is your dependent variable in this model? What are you trying to predict? You're obviously looking for a way to rank plants based on risk but risk of what? Is it a negative sample over a positive sample? So I'm just trying to wrestle with that. And then looking at, you know, presence of these pathogens and the product test, I mean would that be a 0 1 variable and then that would go into whatever this algorithm is? Is the Agency at a point to share that level of detail? Because I'm struggling with --

MS. GREEN: Yeah, I don't think they're quite there but, you know, the idea is we will be completing fairly soon, this fall, the technical paper that will really lay out some of what you're taking a look at.

But the bigger question, and it goes back to exactly what Dr. Engeljohn said. Our goal would be as that algorithm would really relate to public health, and it would be a predicator of risk to

public health.

MR. KOWALCYK: So your dependent variable would be some type of measure of foodborne illness in a time period or --

MS. GREEN: I don't think we're there yet.

DR. ENGELJOHN: We're not capable of doing that now but that's part of the reason why -- what we have is the CDC data which from that we know what serotypes and what subtypes are related to public health. We know from our own inspection results, our *Salmonella* testing program, what is the -- when we do a baseline study or when we do the regulatory test, they tell us different things and how we can use that data, but it gives us some perspective about the exposure of the public to poultry as an example, or to in ready-to-eat products, we have the noncompliance rate of how often we find *Salmonella, E. coli* or *Listeria* in a ready-to-eat product. And so that information gives us some perspective about what the likely exposure is.

What we would use the information for would be that's what we have from the FSIS program and

supplement that with the industry's to see if that more robust amount of information about how much is produced and what the positive rate is, whether or not that gives us a better handle on contributions to the public health. So we use a risk assessment to make those tie ins.

MR. KOWALCYK: Okay.

MR. ELFERING: Okay. It is 4:30. We've got the room all night. We don't? Dr. Harris, I'm going to ask you to answer this first question and come up with some language and then that will give an opportunity for some of the newer members to be able to start looking at the next questions, and we need to start on one of these.

DR. HARRIS: Which question am I answering?

(Laughter.)

MR. ELFERING: All of them. The very first one. In the context of establishing a pilot program, to collect establishment specific industry data for possible use in allocating inspection resources, FSIS requests the Subcommittee to consider the following questions.

What type of industry data would be appropriate for use in a risk-based inspection, RBI algorithm for use in processing establishment? What would you recommend would be our response?

DR. HARRIS: Honestly I'm not sure we have a consensus here. We've asked a lot of questions. I don't know how many of them we've answered.

MR. ELFERING: I agree but I think we have to have a starting point, and then we can discuss it, and I guess I'd like your input from this first, and then we can add to it or subtract from it.

DR. HARRIS: Okay. I'll work on that. Let me formulate here a little bit.

MR. ELFERING: Okay. Do we want to take about a five-minute stretch break while --

MS. GREEN: Thank you.

(Off the record.)

(On the record.)

MR. ELFERING: We'll go back on the record. Dr. Harris --

DR. HARRIS: Yes.

MR. ELFERING: -- has come up with --

DR. HARRIS: Present.

MR. ELFERING: -- has come up with some draft language and Dr. Cannon is going to graciously put it into the computer, and then we can kind of massage it from there. How does that sound?

DR. HARRIS: Let's go with this. I've got some draft bullet points right now that I'm working on putting into language if you will. My intention after the discussion was to start off with sort of the acknowledgement of the difficulty of this, to get your arms around this and to clearly define what it is we mean by data, and understanding that it is extremely variable from one plant to the next on what type of data they have, and acknowledging that the types of data that are listed there in our question would, many of those, especially presence, absence of pathogens, and enumeration data when available, obviously would be some of the most useful data because it is a little more clearly defined, but at the same time, we have to acknowledge that all testing schemes are not created equally, that every plant that is doing testing has designed their

testing scheme with a specific purpose, to accomplish a specific objective and, you know, so every one of these as I list them, you know, I thought of specific caveats that kind of go with those.

So if we're talking about presence or absence of pathogens or their indicators in products, you'd have to acknowledge the limitation of what was the objective when that testing scheme was designed and what do the results actually tell you about that? When talking about volume data, how do we -- the caveat there is, yes, it's useful but the caveat is how do you collect it, how do you define it. It is going to be produced versus shift, and how do you maintain ongoing accuracy of a moving target like that?

Relative to industry data in general, I think there is an ongoing concern about the potential public availability of sensitive industry data and plant specific data that could be either misused, misinterpreted or otherwise harmful if it were released publicly. So again I'm working on, you know, putting that more in paragraph form in complete

sentences. I apologize but it's difficult enough just pulling bullets together out of our discussion.

Other data that potentially could be useful, some of the sanitation effectiveness monitoring tools that are used, the ATP indicators, those are good sort of plus, minus kinds of indicators that might be useful. Again, not everybody uses those though. They're used quite a bit but that varies greatly,

Interventions that are used even in processing establishments, again the caveat there is just telling me that a company uses an intervention means nearly -- it means more than nothing but barely more than nothing. If I don't know how it's being used or how it's effectiveness is being verified on a day-to-day basis, is extremely variable from one plant to the other, and so that's what I came up with so far, Boss.

MR. ELFERING: All right.

MS. GREEN: Kevin and Joe, if we could also discuss a little bit that there was some, some consensus around the thought that we could explore

the volume data maybe in terms of range data a little bit more, that would be great.

MR. ELFERING: Okay.

MS. GREEN: Thank you.

MR. ELFERING: She wants to get out of here with some sort of victory.

(Laughter.)

MS. GREEN: I think it's my boss, Dr. Carol Maczka, don't come back unless you get a pilot program.

DR. HARRIS: The question you didn't ask us is should you do a pilot program to start with but we'd assume you've already answered that question.

(Laughter.)

MS. GREEN: I didn't but many others in the Agency have.

MR. ELFERING: Well, I appreciate Joe working on that, and maybe I can just let him continue on with doing some writing and maybe we can pick up question three.

This is based, of course, on the assumption that we have come up with some kind of consensus,

that there is data that should be collected and that would be available, how would the Agency obtain the data, the mechanism of collection, either by direct from the industry to FSIS databases via the Internet, contract laboratory data or collection as part of an inspection activity by FSIS inspectors of industry records? Michael.

DR. RYBOLT: This is Michael Rybolt. I would just say I think it's going to have to be a variety of sources or mechanisms. I don't think you can dictate one particular mechanism to get that information in. I'm talking about small guys. They may not have Internet access. You know, they may not use a third party laboratory. Maybe they do, I don't know. I guess they would if they're that small. So I think it would probably be a variety of sources or mechanisms to share that information. Whichever way, it would have to be streamlined so that they all seem to come in to get the right information in the same format, but it's going to have to be a variety of mechanisms.

MR. ELFERING: Okay. That's perfect.

MR. FINNEGAN: Yeah, I agree with that. Some of this information, you're going to have to get from the Government inspectors on what is that bullet, down to C. They can e-mail it directly but some of this will come from the inspectors.

MR. ELFERING: Dr. Cannon, were you able to capture all that thought, that particular one? Both of the comments here, and I think that's probably going to be our response. Yes, Isabel?

DR. WALLS: Well, I think we have to be a little careful because this is where we have to consider the criteria for accepting the data given that you might or might not give us any. We're then going to have to decide whether or not we're going to accept it (laughter) not to be picky or anything. But going back to what I was saying earlier about the quality of data, bias in data sets, we do need to be thinking seriously about, you know, how we're going to accept data. If it's coming let's say from a third party laboratory, that's one thing, but if it's coming direct from the industry, that might be looked at differently.

MS. GREEN: Isabel, that's question number 4.

DR. WALLS: Oh, it is? Okay. I'm moving this right along, huh?

(Laughter.)

DR. RYBOLT: This is Michael Rybolt again. The only reason there's going to have to be a variety of mechanisms is because if you don't, I think you might run into Small Business Administration. I mean if we're talking beyond the pilot, we're talking, you know, long term, I think we're going to run into a lot of other issues that may come into play. So you're going to have to leave that option open. That's the reason of my comments and such.

MR. ELFERING: Okay. Then why don't we move onto question 4. If industry data are used, how does FSIS insure data quality? Either by verification by inspectors, use of standardized methods and laboratory certification, or the use of third party audits or any others.

MS. GREEN: And, Kevin, I'll just add there, too, is that I would kind of sense that an

answer similar to number 3 might work here, but we would also like you to try and discuss and capture a little bit about maybe the pros and cons of each, too, even if you go with a variety of methods, it would probably work.

MR. ELFERING: And I think we probably have, you know, some of the pros and cons. I mean in an ideal world, you would want one method of submission but, you know, you've got pros and cons. One of the negative things would be is if you would prefer to have it via Internet, through a secured website or something, and you have a plant that wouldn’t have either the technical ability to be able to do that or the equipment, you've just shown them out of your voluntary program.

So I mean I think you get to the point where the pros and cons are, is that everybody is going to have varied levels of technology, and you don't want to eliminate someone because they don't happen to have that.

MS. GREEN: I think that's an excellent point to capture.

DR. WALLS: And it raises a bigger issue. I mean those facilities that are large and have lots of money, are going to be doing perhaps more testing than those that are very small and don't have a lot of money, and that's an issue I'd like you all to think about, you know. If we're going to use those data, you know, what does that mean for the small and very small who may not be able to provide data. They may not do any testing. I'd like your thoughts on that.

MR. ELFERING: Well, you may also have some small plants that really, if you look at it from a volume standpoint, they may be sampling at the same levels as a large plant. They might be only taking two samples a year but based on their volume, as opposed to a facility that's taking 10 samples a day, it might still equate to how it affects the public, what's the, what is the impact on public health from the standpoint of the volume that's actually going into commerce.

DR. RYBOLT: And that's why it has to be voluntary, just want you said. If they're not taking

samples, this has to be a voluntary, not mandatory system. And an establishment should not be penalized because they don't have data to share as well. We're talking in an RBI system.

DR. WALLS: Again I think this is a very difficult issue, and there's a whole lot of parts to it which is why we need the advice of this Committee. There's a lot in here to think about.

MR. KOWALCYK: This is Michael Kowalcyk. I have a comment that follows up with that is getting a better sense, we're providing recommendations on what data we feel is appropriate for a pilot program and how it would be collected. What's the end game here? Is the end result of the pilot game findings that these types of things, these testing results, these interventions, these volume ranges, will lead to something that will be applied to the industry as a whole? Because to Michael Rybolt's point, it's voluntary because people won't be doing the testing, they have nothing to really volunteer. But if it's going to be applied to the industry and the inspection intensity is going to be allocated based

on these pilots, some consideration needs to be given to, one, is there a need for the data to be collected from a census of all the producers because you want the most accurate ranking? Or are you going to try to apply that ranking based on a sample that might not necessarily be reflective of the overall industry because if plants volunteer this data, that's fine and the pilot would go on and you would get some results from the pilot, but applying those results could become problematic.

MS. GREEN: I think there will definitely be some challenges but I also think that having the data is going to make what we're doing a lot more accurate and a lot more relevant, and having some of this data is also going to allow us to evaluate, even for the voluntary, allow us to evaluate the data that we're estimating I think in a more relevant and appropriate manner, too.

And I'll also turn it over to Dr. Engeljohn because I think in sort of a bigger picture, one of the things you mentioned is I think we see this as also potentially providing -- overcoming some inertia

and sort of just rolling up our sleeves and really starting to look at this. And the example that Dr. Engeljohn gave me had to do with *E. coli* 10 years ago, and how things have changed. So I think we also may be in a bigger picture. I mean I know we're kind of talking about it in the context of RBI, and sort of see it as a way to overcome some inertia about, you know, as you've heard us say before, we can only collect and do a fraction of what industry is doing. And that's some great data that really could go a long way towards protecting public health. So, Dan, do you want to add anything to that or --

DR. ENGELJOHN: Just to be general in terms of how we use it, the point being that as Kim's saying, that hopefully the information that we gather and assess will give us some perspective about what information is relevant to make predictions about how inspection systems impact public health. And where should we put our focus in terms of what should we expect from industry, either through regulation or through other means but to assess that. And these pilot programs are intended to be able to get a

greater data set to make some of those inferences from.

Because ultimately, we would want to be able to find a way, as we view it in the Government anyway, or at least I do as a policymaker, is to credit those operations that are doing more, that can demonstrate that their controls are, in fact, effective, should be given some form of credit for that, so that we would apply our limited resources in those operations who don't have the capacity to do so, and that present a risk.

And so that's the point here, and I think that's part of the example with *E. coli* or with *Listeria*, is those operations that we found ways to effectively demonstrate, that they are controlling, would be where we would want to focus our resources. We would want to do some spot checks there, make sure things continue on in that operation, but to be able to use our limited resources using industry data to supplement that, to make decisions on where we could focus elsewhere. So that's the goal here.

MR. KOWALCYK: My concern still is though

if it is voluntary, you're risking getting a skewed sample of data from industry just based on who has the capability to provide it. It's not a malicious thing or anything like that. It's just certain producers have the wherewithal to provide it, whereas you could be missing a large slice of the regulated industry and applying the results from this pilot program to that population and that I would argue will cause problems either possibly legal or taking regulatory action based on something that really wasn't developed on that type of plant.

So I would recommend that it may have to be voluntary but if it could be more of a solicited sample plan that the Agency would try to go out and get a representative sample of plants, that may mean 100 or 200 plants across, you know, product type and size based on your volume metrics.

MS. GREEN: I think that's something we could work on in this. That's a good point, and I've noted it. Thank you, Michael.

MR. ELFERING: Getting back to formulating an answer or response for question 4, for example,

for the -- if a plant is doing *Listeria* testing, and you're using that as their method of controlling *Listeria* as environmental testing, what do you do now? Do you require that it be done using standardized methods? Does it have to be in a certified laboratory or could I take my *Listeria* samples and sent them to ABC Labs and are you interested at all right now in what methods are used or whether or not the lab is certified?

DR. ENGELJOHN: The issue of *Listeria* is a little different than *E. coli* and *E. coli* is a little easier to explain. So if I could use it for that particular program.

We don't have criteria for what method you use or how frequently you test, but industry itself has jointly, at least the larger operations, have jointly come to an agreement in terms of standardized. They use a minimum level of testing, a type of testing in order to have some consistency across the industry, the excised tissue from whole muscle cuts instead of using core testing. They use what we call an N60 test to get at the issue of

sampling representative portions of their production lots and they do 100 percent of that. They use methodologies that are some cases more sensitive than the FSIS method but the issue is that they have some relative standardization and collectively that provides some level of protection. We don't mandate a level but if we find the organism in the product, then the issue becomes one of just if the industry is using something less sensitive or less specific than what we are, then their vulnerability is that their food safety system isn't designed to actually find and prevent the adulterer from getting in the marketplace. So we don't specify that but one recommendation could be that there should be some protocols or options or guidance given to try to standardize things if that would be something that would be helpful.

MR. FINNEGAN: Mike Finnegan. In previous testing, and I know the plants had to have their method AOAC approved. Is that still a current -- the methodology of AOAC?

DR. ENGELJOHN: The industry can use any

method that they choose to use that, for their system, is designed to give them whatever confidence they need that the product they produce meets the regulatory requirements. So that's the requirement. We don't have a regulatory requirement for what you must do. We just tell you what your vulnerability is if you don't use that.

MR. ELFERING: But because of that, you're going to have varied levels, you know, you're going to have some laboratories that are using AOAC or BAM methods, and so how do you establish that then? Or like you had said. Maybe somebody has developed a more sensitive test or testing for *Salmonella* that is more sensitive than what FDA or FSIS is using.

DR. ENGELJOHN: So it might/ would be that perhaps the recommendation would be that that kind of information should probably be collected so that you can make some assessment of what it was designed to do, what level of sensitivity if those are the kinds of things that you think should be included, the point being, that industry is going to use whatever they're using and they're doing that today. And our

perspective is to get some sense of what is, in fact, being produced and is exposing the American public to pathogens. So we don't have regulatorily defined minimum criteria that must be there. That isn't our intention right now.

MR. ELFERING: So you would want them to include their methodology with --

DR. ENGELJOHN: Recommend that that should be something that we should collect, relevant things that may impact how you interpret the data.

MR. ELFERING: So our recommendation would very likely be that in addition to any laboratory or any results that are provided, that the methods used to determine either presence or absence, serology would be included with the submission?

DR. WALLS: And again, I think that's the exact type of thing we're looking for from this Committee. What do you advise and certainly that seems to be a very, very good idea, that we know what methodology was used and the sensitivity of the test. That's the kind of things this Committee should be recommending.

MR. ELFERING: Well, I think one of the things though, too, is methods change daily. I mean there is laboratories out there that are doing new methodology that are far surpassing last year's technology. And so it's a very changing world as far as science. Yes.

DR. NEGRON-BRAVO: I have a question. This is Edna Negron. I was under the impression that when the industry does tests they will have to give the same kind of -- use the same protocols and methodology that the Agency uses, even though I think hearing from you that they may also use another kind of information or test that might provide them the information that they need. And I understand that maybe that could be of value because maybe that new methodology could be considered as valuable information and methodology to be used by the Agency. But still if the information is not the same information that the Agency uses because it happened once in Puerto Rico, the plant say we do tests, we do tests and it's negative and the Agency says it's positive, of course, they were not using FSIS/USDA

methodology. They were using a method for another kind of sample. Once they started using FSIS, they correlated samples for positive data, positive.

So what do we want? Do we want to have information that if the Agency's collecting much, you know, kind of, the same feeling or do we want to explore new methodology but the Agency's getting a new supply or may be giving them some resource in order to do interventions. Because it's working for them to control the pathogens. So we need to answer before we select. Of course, we can just ask what are you using, and then use that as a basis of what are we going to use the information, how we are going to use it because it will be very relevant.

MR. ELFERING: Ms. Nestor.

MS. NESTOR: Felicia Nestor, Food and Water Watch. Sort of building on that point, I mean from a consumer's standpoint, you know, I don't think I'm only speaking for myself when I say, you know, there's almost something oxymoronic about industry data. Generally, we don't want to put our safety in the hands of someone who stands to make a profit by

cutting corners. So we don't want to trust the industry. No personal attacks on anybody, you know, I'm not casting any aspersions on anyone, you know. It's just we want to be as certain as we can be that this data is valid.

And I don't know. Has the Agency ever demonstrated by doing correlation studies that as a general matter, industry data correlates with FSIS data? I mean I've been speaking to inspectors since 1995 and, you know, they tell me that sometimes they see the plant taking the test and the way you collect the sample can determine whether or not it's going to be a viable sample and a legitimate sample. And so I mean I would like to see it demonstrated that as a general matter, the industry data correlates within some reasonable expected level of confidence with FSIS data. And then if that's the case, and consumers, you know, agree to accept industry data, I would like to know that there is some process by which FSIS checks periodically a plant's data by, you know, whatever it is. Whatever method it is that, you know, the inspector at his or her discretion can

go in and, you know, when they see the plant has pulled the sample that day, to go and pull their own sample and not to tell the plant what their result was, and then to see on, you know, after a period of time, how many times was the plant sample result the same as the FSIS sample result.

MR. ELFERING: I think there's a lot of variabilities in all of that, and I think what Dr. Engeljohn is probably alluding to is that the Agency's position, it is really the responsibility of the industry to demonstrate that you're producing a safe product. And that's why some of the old regulations, very prescriptive regulations on the construction of plants were eliminated because they were really in some regards holding back industry that were developing much better equipment and maybe even some situations where they had better methodologies for doing microbiological work as well.

MS. NESTOR: I understand.

MR. ELFERING: Let me finish. There's also variabilities in who is taking the sample, and inspection personnel are not the greatest samplers.

I've seen atrocious sample techniques from inspection personnel and, you know, in many cases, absence of evidence is not evidence of absence. And correlation on some of those things are not always going to be real easy to do.

MS. NESTOR: Well, what, you know, it may be industry's responsibility to demonstrate that they're producing a safe product, but FSIS' responsibility to the consumer is that FSIS has an inspection system that is reliably protecting the consumer. And so I think FSIS has to demonstrate to the consumer that whatever it is doing sufficiently protects the consumer.

And while there may be variability in, you know, because of who's taking -- I mean it doesn't make me feel better that some of the inspectors don't take the sample, but it does concern me and I think consumers should know whether or not industry's results and FSIS' results are not the same.

I mean if what you're telling me is that we really can't expect them to be the same at all, then that really concerns me. I mean I would assume if

you're using a sampling program as representative of what that process is doing, that two separate sampling programs, if the goal is the same, to find out how the process control is, that you should come up with the same result.

And I'm not talking about on one particular chicken. I'm talking about, you know, over time.

MR. ELFERING: And I think we could discuss this for a long period of time, and I think one of the things that the Agency is, is probably wanting is they're not necessarily wanting to set a standard but they do want the option of being able to see the methodology that is being used, so they can review it and make a determination from that standpoint as well.

And again, remember this is a voluntary program and it's something that's not mandatory.

MR. FINNEGAN: Mike Finnegan. In answer to question number 4, I think we should state that the pilot plant submits the methodology they use and, Isabel, if they did that, could you -- would that -- how did they word it here? Insure the integrity.

DR. WALLS: Well, I think it would go a long way to determining, you know, if the method is valid. I mean if it's an AOAC approved method, I think we would be very comfortable with that. And if it's not, then we would want to see, you know, how it was validated or what the sensitivity and specificity are. But I think that's one part of it.

MR. ELFERING: Brian, did you have --

MR. COVINGTON: Well, I was -- it's pretty much a follow up to that. I think there's some precedence when it comes to the minimums that we could recommend for acceptability with the EMLG and the sensitivity and specificity of tests that are out there being used by industry as far as that goes. And then I think there's probably some other minimum criteria that we could set for the laboratories that are in use because most third party labs have some type of accreditation, either some type of ISO because it's good for their business and there may be a chance to have discussions on what those minimums may be, that would be acceptable to all parties involved.

MR. ELFERING: Dr. Cannon, were you able to get those thoughts for question 4 or do we need to have a little bit more clarification?

DR. CANNON: I --

MR. ELFERING: I thought we were going until 7:30. I'm just kidding. Just kidding.

(Laughter.)

MS. WALLS: We do have an hour in the morning, folks. So we start again at 8:30. We have a whole hour in the morning to go over this again. So you can think about it tonight, but we would encourage you to think about, you know, what we really want to do, I think Dan put it very well, is to see how and whether we can use industry data to supplement our data to inform our decision making, and even if we can just look at one part of that, say volume data, maybe that's something that we can agree upon that we could look at, and in a very small pilot, see whether we can use it to inform our decision making. I think, you know, it's a start, you know, and then we can start working through these, you know, criteria for accepting data and

things like that, which might be something that might be much less sensitive than the microbiological data which I would anticipate could be very, very difficult right now given that we can't necessarily protect it.

So why don't we start with something simple like the volume data which maybe we can agree is something that industry would be willing to share maybe, and maybe we can think about some criteria, you know, on how we can share it in a very small pilot, voluntary basis, so that we can take a look at that and, and see whether it can inform our decision making.

MR. COVINGTON: And I would just want to reiterate, and I think Michael's probably about to say, I caution the use of a small pilot in that it is representative of what we're trying to accomplish and we had that goal in mind.

DR. WALLS: I agree, and again I think if we can conceptually agree on what the pilot might look like, and then we can start ironing out the details. How do we make it representative? How do

we make it statistically significant? But right now we're just talking in circles. So I think if we could sort of focus, you know, on something very narrow and specific, and then look at what criteria do we need to put down so that industry's willing to share it and consumers are willing to accept it, we're in the middle here. We've got to get both of you, smiling at each other and say, hey, yes.

So I would say, why don't we pick something that we think we can all agree on and then start talking about criteria that would make it statistically, you know, representative and acceptable to industry to give to us and acceptable to consumers to accept it so that we can see if we can actually make this work. And then we're dealing with a concrete -- I'm a concrete person. I can't deal in the abstract. We're dealing with some concrete issues, we can come up with some concrete criteria for making it, you know, what sort of products do we need to look at to make it representative? How many plants do we need to have to make it representative? So that we can, you know,

we can be dealing with concrete.

MR. ELFERING: Michael.

MR. KOWALCYK: Brian got part of what I wanted to say. What I wanted to add to that was in the context of the fourth question about FSIS personnel insuring that the data's accurate. I think for a pilot program, and I agree as well, that we should start with something simple because what it does is if this is something that would be scaled out to the industry, there needs to be a more rigorous standard by which that data is scrutinized. And it's, in my opinion, game changing for FSIS, as your personnel needs to be educated and equipped to audit essentially the data they would receive, if they were ever to receive industry data that would then be used for regulatory purposes. Felicia brings up a good point about testing. There's probably some very good quality control guys in industry and gals in industry doing things that are cutting edge that as a consumer I'd like to see become the goal standard. But with that said, there needs to be an objective standard and that, you know, I see as the role of FSIS is to

insure that the data is accurate and it's being collected for the right purpose.

So I think there's an opportunity with respect to question 4, and even if it is collecting volume data, the Agency should look at ways to equip their field force to validate the data they're receiving and to start developing best practices, so that if it was to be rolled out, that foundation would be there.

MR. ELFERING: Joe.

DR. HARRIS: Mr. Chairman, I was just going to suggest in the interest of time, that we do have an opportunity to get back together in the morning for an hour --

MR. ELFERING: Yes.

DR. HARRIS: -- from 8:30 to 9:30, and I've given all my hen scratching on that first question that I finally pulled together to Loraine, and maybe in the morning, we would have an opportunity to then go back through it as a group.

MR. ELFERING: I think that would be a very good idea. I would appreciate that.

DR. HARRIS: And have a chance to look at what all we got on paper and figure out where to go from there.

MR. ELFERING: Okay. Mr. Yancy, did you have a comment yet?

DR. YANCY: I think that's a wonderful idea.

MR. ELFERING: Let's reconvene here at 8:30 tomorrow morning, and we'll go. I really want to thank the Committee and especially Joe for taking on that question.

DR. HARRIS: I was happy to volunteer.

(Laughter.)

MR. ELFERING: And I appreciate the FSIS staff available and also any -- all of you, all of you for your comments, they're always going to be welcome, and we appreciate your help and guidance with this as well. Thank you all. See you in the morning.

(Whereupon, at 5:26 p.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

NATIONAL ADVISORY COMMITTEE ON

MEAT AND POULTRY INSPECTION

SUBCOMMITTEE 2

PILOT PROJECT TO EXPLORE MECHANISMS

FOR SHARING INDUSTRY DATA WITH FSIS

Arlington, Virginia

August 8, 2007

were held as herein appears, and that this is the original transcription thereof for the files of the United States Department of Agriculture, Food Safety and Inspection Service.

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DOMINICO QUATTROCIOCCHI, Reporter

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